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| APPLICATION NO.                   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------|-------------|----------------------|---------------------|------------------|
| 08/648,092                        | 06/21/1996  | JOHNSTON W. MCAVOY   | UNSYD-39709         | 8661             |
| 24201                             | 7590        | 01/26/2005           | EXAMINER            |                  |
| FULWIDER PATTON LEE & UTECHT, LLP |             |                      | FAY, ZOHREH A       |                  |
| HOWARD HUGHES CENTER              |             |                      | ART UNIT            | PAPER NUMBER     |
| 6060 CENTER DRIVE                 |             |                      | 1614                |                  |
| TENTH FLOOR                       |             |                      |                     |                  |
| LOS ANGELES, CA 90045             |             |                      |                     |                  |
| DATE MAILED: 01/26/2005           |             |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 08/648,092             | MCAVOY ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Zohreh Fay             | 1614                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 14-33 is/are pending in the application.
- 4a) Of the above claim(s) 29-33 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 14-28 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____ .   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: ____ .                                   |

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Claims 14-28 are presented for examination.

Claims 30-33 are withdrawn from consideration.

Claims 34-38 have been canceled.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of certain inhibitors of TGFB for the inhibition of cataract or after cataract formation, does not reasonably provide enablement for the use of all inhibitors of TGFB for the inhibition of such disorders. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are:

1) The nature of the invention:

The claims are drawn to a method of inhibiting TGFB induced cataract or after cataract formation using one or more of inhibitors of TGFB.

2) The state of the prior art:

The prior art does not recognize that the treatment of cataract is easily accomplished. According to Lance Current Diagnosis & Treatment, cataract is usually removed with one of the techniques in which the delicate posterior capsules remains.

This may, however, call for subsequent laser treatment if the posterior capsules opacifies. It is routine practice to implant an intraocular lens during the surgery. Thus, without sufficient guidance by the instant specification, and without any guidance by the state of the art, there would be undue experimentation for a person skilled in the art to identify all TGFB inhibitors, which are capable of inhibiting cataract or formation of after cataract.

3) The relative skill of those in the art:

The relative skill of those in the art is high.

4) The predictability and unpredictability of the art:

The unpredictability of the pharmaceutical and chemical art is high.

5) The breadth of the claims:

The claims are very broad and encompass the use of any TGFB inhibitor for the inhibition of cataract or after cataract formation.

6) The amount of direction or guidance presented:

Applicant's specification provides guidance and it is only enabled for the inhibition of cataract or after cataract formation using certain TGFB inhibitors. However, the specification provides no guidance, to enable one of ordinary skilled in the art to use the invention commensurate in scope with the claims. *In re Dreshfield*, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemical and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical

combinations included in the claims are capable of accomplishing the desired results".

Applicant's specification does not set forth a representative number of examples TGFB inhibitors, which are capable of inhibiting cataract or after cataract formation.

7) The presence or absence of working examples:

The examples in applicant's specification are drawn to the use of only two TGFB inhibitors in inhibiting cataract or the formation of after cataract.

8) The quantity of experimentation necessary:

Since compound structure and activity for each pharmaceutical use must be determined from case to case by painstaking experimental study, one of ordinary skill in the art would be burdened with undue experimentation to determine all TGFB inhibitors, which are capable of inhibiting cataract or formation of after cataract.

Claims 19-23 are rejected under 35 U.S.C. 102 (b) as being anticipated by WO 92/17206. WO Patent teaches the use the claim designated compounds in a pharmaceutical formulation. See the claims and the entire document. The above reference makes clear that the claimed composition is old and well known. Applicant's attention is drawn to *In re Dillon*, 16 USPQ2nd 1897 at 1900 (CFAC 1990). The court sitting in banc ruled that the recitation of a new utility for an old and well-known composition does not render that composition new.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Fay whose telephone number is (571) 272-0573. The examiner can normally be reached on 9:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z.F

A handwritten signature in black ink, appearing to read "Zahid Fay".